

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In Re: Bair Hugger  
Forced Air Warming Devices  
Products Liability Litigation

Case No. 15-md-2666 (JNE/DTS)

**REVISED  
CATAGORIZATION ORDER**

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Following productive discussion with the parties, the Court has drafted a protocol, attached as Exhibit A, for categorizing cases in the MDL based upon (1) proof of product identification and (2) applicability of any relevant statute of limitations or statute of repose.

The parties are HEREBY ORDERED to follow the procedures outlined in the attached protocol.

Dated: May 17, 2019

s/David T. Schultz  
DAVID T. SCHULTZ  
United States Magistrate Judge

## I. Product ID Classification

### A. Purpose and General Guidelines.

The Court and the parties have engaged in a process to categorize the cases in the MDL by placing them into various “buckets.” It is the intent of this exercise that categorizing the cases will simplify case management, facilitate dismissal of cases or elimination of issues for jury or court resolution, and assist the court and the parties in the process of bellwether selection. It is also expected that the process is necessary to eventual settlement of the cases in the MDL, should that occur.

As a corollary to these general principles, it is understood that each party shall have its full complement of due process and discovery rights.

### B. Principles relating to Product Use screening.

The first effort at categorization will be to place the cases into one of three buckets relating to proof of product use so as to eliminate those cases in which there is inadequate evidence of product use to sustain the action and to identify those cases in which there is no reasonable dispute that the Bair Hugger was in fact used during the relevant surgery. However, it is anticipated that the majority of cases in the MDL will fall into a third category wherein the parties dispute the evidence of product use and the issue will require additional discovery, potential motion practice, or submission to the fact-finder.

### C. Product Use Categories.

#### 1. Bucket 1: Insufficient evidence of product use to sustain the action.

This bucket will contain those cases in which there is insufficient evidence that the Bair Hugger was used during the relevant surgery to sustain the action. Such cases may include:

- Cases in which the medical records unambiguously state that the patient was not warmed during the surgery.
- Cases where the medical/surgical/billing records affirmatively indicate that the patient was warmed using a competing technology either by brand name or unambiguous reference to a different technology (e.g. “warming mattress”) and there is no other indication of Bair Hugger use.

- Cases in which there is no documentary evidence relating to patient warming product use during surgery. (A patient who claims personal recollection of product use in the absence of documentary evidence relating to warming during surgery must file a detailed declaration specifying the basis for that recollection. These cases will be subject to further process—see below.).

## 2. Bucket 2: Conclusive evidence of Bair Hugger use.

This bucket will contain those cases in which contemporary documentary evidence of Bair Hugger use is unambiguous. Medical, surgical and/or billing records are appropriate types of evidence for this purpose, but other documentary evidence may also suffice. By way of illustration and not limitation, such cases will include:

- Cases in which an individualized notation in the patient's chart indicates use of the Bair Hugger during the relevant surgery. Examples of this may include a handwritten note by the surgeon or the anesthesiologist in the patient's chart; a billing statement in which the Bair Hugger is an itemized charge by name. A "check-the-box" notation will not in and of itself suffice to conclusively establish Bair Hugger use during surgery (such cases will be placed into Bucket 3 described below).

## 3. Bucket 3: Evidence of Bair Hugger use that is not dispositive.

The court anticipates that this bucket will be the one into which the majority of cases will be placed. Cases of this type include:

- Cases where Bair Hugger use is indicated by a brand-specific "check-box" form, but in which the use is not specifically confirmed elsewhere in the record.
- Cases in which the Bair Hugger is specifically referenced in the medical records as being used during surgery, but other hospital records or 3M internal records call that information into question.
- Cases in which the records reference warming, forced-air warming, or FAW without corroborating evidence that the technology used was a Bair Hugger system.

- Cases in which the contemporary evidence is inconsistent as to Bair Hugger product use.

## D. Process for placing the cases into Categories.

### 1. Stage 1: Plaintiff identification:

Within **60 DAYS** of the date of this order, each plaintiff's counsel shall review the evidence on which they have based their allegation of product use. Based on that review, each plaintiff's counsel will place their cases into one of the three categories identified above. It is expected that each plaintiff's counsel will, as an officer of the court, place those cases for which the evidence of Bair Hugger is insufficient to sustain the action into Bucket 1.

The remaining cases shall be placed into either Bucket 2 (conclusive evidence) or Bucket 3 (disputed use). For those cases placed into Buckets 2 and 3, plaintiff's counsel shall provide a one-line summary of the evidence on which they base their classification with specific reference to pages of document(s) relied upon and a copy of the document(s)/pages relied upon. This information shall be included in a spreadsheet—one spreadsheet for each bucket classification.

### 2. Stage 2: Defendants' response.

Within **60 DAYS** of receiving Plaintiffs' spreadsheets, Defendants shall respond in the following manner:

- As to cases placed in Bucket 2 (conclusive evidence of product use), Defendants may object as to the placement of any case into this bucket by providing Plaintiff's counsel a statement of reasons as to why Defendants believe product use is not conclusively established, along with copies of *any* documents that bear on the question (whether favorable to Defendant's position or not). Plaintiffs may, within **30 DAYS** invoke the summary disposition process outlined below. If Plaintiff does not invoke that process, the case will automatically be moved into Bucket 3 (disputed product use).
- As to cases placed into Bucket 3 (disputed evidence of product use) which Defendants believe in good faith belong in Bucket 1 (insufficient evidence of product use), Defendants may invoke the summary disposition process outlined below. Plaintiff will have **30 DAYS** to respond to Defendant's objection.

- As to all cases in which the Defendant agrees with the Plaintiffs' categorization, Defendants shall indicate that agreement on the spreadsheet.

## E. Resolution Process.

Once the product use categorization process has been completed, the following resolution process will be undertaken.

1. Cases as to which the parties agree regarding bucket placement.
  - Cases placed into Bucket 1 by Plaintiffs will be dismissed with prejudice by the court without further proceedings.
  - As to cases placed into Bucket 2 the Defendant shall file a stipulation of product use so as to remove that issue from further discovery and from dispute at trial.
  - Cases placed into bucket 3 shall proceed on the issue of product use in the ordinary fashion (i.e. discovery, motion practice, submission to jury at trial if appropriate after motion practice).
2. Cases as to which the parties disagree regarding bucket placement.
  - As to any case placed by Plaintiff into Bucket 3 (disputed evidence of product use) or Bucket 2 (conclusive evidence of product use) which Defendant claims should be in Bucket 1 (insufficient evidence of product use), Defendant may seek summary disposition as follows. Defendant shall notify Plaintiff in writing of the reasons for the dispute and shall provide copies of all documents on which Defendant relies to support its position. Plaintiff shall have **30 DAYS** to either agree to Defendant's categorization or notify Defendant that s/he does not agree. If Plaintiff does not agree, Defendant may, within **10 DAYS** of receipt of Plaintiff's notification, seek summary disposition from the court by filing a letter, no longer than 5 pages in length, stating its reasons why the case should be placed into Bucket 1 and dismissed, along with copies of all documents on which it relies supporting its position. Plaintiff shall have **10 DAYS** from receipt of this letter to reply in the same fashion. Once the issue is submitted, the Court will either place the case into Bucket 1 for

dismissal or deny Defendant's request, in which case the case shall remain in Bucket 3 (disputed evidence of product use).

- As to any case placed by plaintiff into Bucket 2 (conclusive evidence of product use) which Defendant believes should be placed into Bucket 3 (disputed evidence of product use), the parties shall follow the same procedure outlined immediately above. If the Plaintiff agrees the case should be moved into Bucket 3, s/he shall notify the Defendant of same and the case shall be moved into Bucket 3. If Plaintiff disagrees with Defendant, s/he shall notify the Defendant, who shall either accept the Plaintiff's position or, within **10 DAYS**, commence the Court's summary disposition process described above.

## II. Statute of Repose / Statute of Limitation Classification

### A. Purpose.

The purpose of this categorization is to identify those cases which are indisputably untimely and should be dismissed, and those cases which are indisputably timely. Those cases in which the application of the statute of repose or the statute of limitations is in dispute will be identified for further factual development and/or motion practice.

### B. Categories.

#### 1. Bucket 1: Cases outside the statute of repose period.

This bucket will contain those cases in which the action was commenced after the period allowed under the applicable **statute of repose**. It is understood that the following states have statutes of repose applicable to product liability actions of this nature: Illinois (10 years), Indiana (10 years), Iowa (15 years), Florida (12 years), Georgia (10 years), Kentucky (8 years), North Carolina (6 years), Ohio (10 years), Oregon (8 years), Tennessee (10 years), and Texas (15 years).

Within **10 DAYS** of the date of this order the parties shall meet and confer for the purpose of identifying and agreeing upon the period of repose for each state that has an applicable statute of repose and the event(s) which trigger the running of the statute of repose. The parties shall finalize this information in an agreed-upon stipulation/document.

## 2. Bucket 2: Cases that are indisputably timely.

This bucket will contain all cases that were filed indisputably within the relevant statue-of-limitations period measured from the date of the index surgery to commencement of the action.

## 3. Buckets 3-5: Cases of disputed timeliness - SOL.

These buckets will contain all cases that were not filed within certain periods as measured from the date of the index surgery to commencement of the action, without accounting for discovery rule or fraudulent concealment. The buckets are measured and categorized by the length of time beyond the length of the statute of limitations period as measured from the date of the index surgery: Bucket 3: less than 2 years; Bucket 4: 2-5 years; Bucket 5: more than 5 years.

# C. Process.

## 1. Initial Classification.

Within **30 DAYS** of this order, Defendant(s) shall place each case within one of the five categories described above. (Each category shall be logged separately in its own excel spreadsheet.)

## 2. No Objection.

Plaintiff shall have **30 DAYS** to raise objections to any categorization made by Defendant(s). As to those cases for which no objection is lodged the following dispositions will occur:

Bucket 1 cases (SOR) will be dismissed 30 days following the end of the objection period.

Buckets 2 - 5 cases: no disposition is required on cases placed in this bucket. Any defense of untimeliness may be raised and addressed in the ordinary course.

### 3. Objections.

Plaintiff shall have **30 days** to raise objections to any categorization made by Defendant(s). As to those cases to which Plaintiff objects, Plaintiff shall, within **30 days**, provide defendant in writing the following information: which statute-of-limitations bucket Plaintiff believes the case should be placed into, the reason for this belief, and the documents and facts on which Plaintiff relies for this position.

If Defendant agrees with Plaintiff's objection, the case shall be moved into the agreed bucket.

If Defendant disagrees with Plaintiff's objection in writing within **10 DAYS**, the parties may submit this dispute to the Court as follows.

Within **30 DAYS** of receiving Plaintiff's objection, Defendant may submit a letter of up to 5 pages to the Court stating its reasons for its position and attaching any documents or exhibits supporting its position. Plaintiff shall have **30 DAYS** to respond in like manner, at which time the Court will deem the dispute submitted. The Court will sustain the objection unless Defendant has proven its position by a preponderance of the evidence.

## III. Classification of Remaining Cases

Once the cases have been sorted as to product use and timeliness, the parties will create four separate Excel spreadsheets.

### A. Spreadsheets.

Spreadsheet 1: Conclusive product use, conclusively timely filed.

Spreadsheet 2: Conclusive product use, dispute as to whether case was timely filed.

Spreadsheet 3: Disputed product use, conclusively timely filed.

Spreadsheet 4: Disputed product use, dispute as to whether case was timely filed.

Defendants shall prepare the spreadsheets above. Each spreadsheet shall include an additional column with the heading "SOR," and for each case Defendants shall enter either a "yes" or "no" in this column indicating whether they reserve their right to assert the statute of repose.

## B. Grids.

For each spreadsheet above, two additional columns shall be added with the headings “Latency” and “Injury.” For each case, Plaintiffs shall note the Latency period (index surgery to date of diagnosis of infection) and Injury. The Latency periods will be: 30 days, 31-90 days, 91-365 days, 366-729 days, and 730+ days. Plaintiffs shall provide Defendants the specific documented source supporting both Latency and Injury for each case.

*Latency Period (index surgery to date of d(x))*

Latency Injury	Type of symptoms & surgery (hip, knee or other)	30 days	31-60 days	61-90 days	91-365 days	366-729 days	730+ days
Death							
Amputation							
2 Stage Revision							
Single Stage Total							
Single Stage Partial							
Irrigation & Debridement							
Antibiotic							
Other							

